

GIM Research

Patient Decision-Making

Title: An Intervention to Enhance CHD Risk Factor Modification: The Heart to Heart Feasibility Study

Status: Phase I (*completed*), Phase II (*Awaiting IRB approval*)

Date: January 1, 2005-July 31, 2010

Study Design: Pilot Randomized Controlled Trial

Project Brief: This study will provide patients with information about their global coronary heart disease (CHD) risk and effective risk reducing strategies to allow them to make appropriate decisions and initiate and maintain behavior (i.e. taking medication) that will result in the reduction of CHD risk.

Project Objectives/Purpose Statement:

Coronary heart disease (CHD) is the leading cause of death in the U.S., but less than half of all patients at risk use effective prevention strategies for each CHD risk factor. Involving patients as active partners in decision-making may improve adherence to effective CHD prevention strategies and global CHD risk may facilitate involvement.

The purpose of this study is to perform a feasibility trial of a multi-component intervention in 200 patients at UNC's General Internal Medicine Clinic. Ultimately, this study will provide preliminary data for a multi-site randomized controlled trial.

Project Description:

Our research program is divided into two phases. Phase 1 (which has already been completed) involves the collection of qualitative data from patients and the development of our multi-component CHD intervention. Phase 2 (which is due to start mid-May 2007) is a feasibility study with 200 patients enrolled at one university internal medicine practice.

In phase 2, we will conduct a pilot randomized trial of patient adherence to self-chosen risk-reducing strategies. In this trial, we will determine our ability to recruit patients at moderate and high risk of CHD; deliver the CHD intervention in a busy practice setting; and measure study outcomes, including patients' decision-making plans, self-reported adherence to medications, and changes in global CHD risk.

Inclusion Criteria: Our study population will include a convenience sample of 200 adult patients, ages 40-79, from the General Internal Medicine Clinic at the University of North Carolina at Chapel Hill. Patients will be recruited to be at moderate (6-20%) or high (>20%) risk of CHD as defined by current evidence and practice-based guidelines for aspirin and cholesterol.

Exclusion Criteria: Our current exclusion criteria are:

- Known cardiovascular disease (including previous myocardial infarction, previous coronary artery bypass graft or percutaneous coronary intervention, angina, previous TIA or stroke, peripheral vascular disease, or congestive heart failure)
- Diabetes
- Low global risk of CHD (<6%)
- Dementia or other severe cognitive dysfunction
- Blindness
- Serious medical illnesses that would make patient a poor candidate for screening (including renal failure, liver cirrhosis, HIV, non-skin cancer, and any other illness for which their life expectancy is projected at less than five-years)
- Inability to speak and understand English
- Participation in our preliminary study or cognitive testing of the components of the intervention

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Key Contacts

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Links

- <http://med-decisions.com/>
- <http://www.nhlbi.nih.gov/>

Publications

- Sheridan, S.L., Shadle, J., Simpson, R.J., and Pignone, M.P. *The impact of a decision aid about heart disease prevention on patients' discussions with their doctor and their plans for prevention: a pilot randomized trial.* BMC Health Services Research. (Accepted September 27, 2006)